

WHAT IS CLAIMED IS:

1. A stent or stented graft compliance test assembly, comprising:

an animal tissue tube having opposed free ends and defining an inner lumen;

a pre-tester including fixtures adapted to sealingly couple to the free ends of the

animal tissue tube and a fluid supply in communication with at least one of the fixtures and

the animal tissue tube lumen; and

a stent or stented graft positioned within the animal tissue tube.

2. The assembly of claim 1, wherein the animal tissue is porcine. 5662705 column 1, 33-39

3. The assembly of claim 2, wherein the animal tissue tube is a section of porcine aorta with any side branches ligated. 5662705

4. The assembly of claim 1, further including a pulsatile pumping system for the fluid supply that pressurizes the animal tissue tube lumen to pressures found in the human vascular system. 5670708 112 Human

5. The assembly of claim 1, further including a sensor for measuring the exterior diameter of the animal tissue tube. 5670708 column 6, lines 30-45

6. The assembly of claim 5, wherein the sensor is a non-contact sensor. WO 02/32224 p17 para 1

7. The assembly of claim 6, wherein the sensor is a laser micrometer. WO 02/32224 p17 para 1

8. The assembly of claim 5, wherein the assembly includes a stented graft having multiple individual wires at axially spaced locations along an outer graft tube, and wherein the sensor is positioned to measure the exterior diameter of the animal tissue tube at the axially spaced locations. WO 02/32224 p17 para 1 lines 9

9. A method of testing the compliance of a stent or stented graft, comprising:

sealingly coupling opposed free ends of an animal tissue tube onto fixtures of a pre-tester, the animal tissue tube having a lumen;

positioning a stent or stented graft within the animal tissue tube; and

providing a fluid to the animal tissue tube lumen via at least one of the fixtures.

10. The method of claim 9, further including pressurizing the fluid in the animal tissue tube lumen to pulsatile pressures found in the human vascular system. 5670708 column 5-9

11. The method of claim 10, further including measuring the exterior diameter of the animal tissue tube at different pressures. *5670708 column 6 line 54*

12. The method of claim 11, further including:

recording the data on the measured exterior diameter of the animal tissue tube;

sealingly coupling opposed free ends of a synthetic tube onto fixtures of a tester, the synthetic tube having a lumen; *5670708*

positioning within the synthetic tube a stent or stented graft of the same kind as was pre-tested in the animal tissue tube; *5670708 find*

providing a fluid to the synthetic tube lumen via at least one of the fixtures of the tester; *5670708*

pressurizing the fluid in the synthetic tube lumen at a pulsed rate; and *5670708 column 6*

measuring the exterior diameter of the synthetic tube and controlling the fluid pressure based on the recorded data. *5670708 column 6 line 53*

13. The method of claim 12, wherein the fluid pressure within the synthetic tube lumen is controlled to expand the diameter of the synthetic tube to the same dimension as the measured diameter of the exterior diameter of the animal tissue tube. *find*

14. The method of claim 13, wherein the animal tissue tube lumen is pressurized to both normal and abnormal pulsatile pressures found in the human vascular system, and the synthetic tube lumen is pressurized at a pulsed rate based on the measured exterior diameter of the animal tissue tube to simulate both normal and abnormal compliance conditions. *column 6, lines 46-54*

15. The method of claim 9, wherein the step of positioning comprises positioning in the animal tissue tube a stented graft having multiple individual wires at axially spaced locations along an outer graft tube, and further including:

pressurizing the fluid in the animal tissue tube lumen to pulsatile pressures found in the human vascular system; and

measuring the exterior diameter of the animal tissue tube at the axially spaced locations and at different pressures.

16. The method of claim 15, further including:

*5670708* recording the data on the measured exterior diameter of the animal tissue tube;

sealingly coupling opposed free ends of a synthetic tube onto fixtures of a tester, the synthetic tube having a lumen; 5670708

positioning within the synthetic tube a stented graft of the same kind as was pre-tested in the animal tissue tube; 5670708

5 providing a fluid to the synthetic tube lumen via at least one of the fixtures of the tester; 5670708

pressurizing the fluid in the synthetic tube lumen at a pulsed rate; and 5670708

measuring the exterior diameter of the synthetic tube at the axially spaced locations while controlling the fluid pressure based on the recorded data such that the diameters of the synthetic tube at the axially spaced locations expands to the same dimensions as the measured diameter of the exterior diameter of the animal tissue tube at the axially spaced locations.

17. A method of testing the compliance of a stent or stented graft, comprising:

sealingly coupling opposed free ends of a pre-tester tube onto fixtures of a pre-tester, the pre-tester tube having a lumen; 5670708

positioning a stent or stented graft within the pre-tester tube; 5670708

providing a fluid to the pre-tester tube lumen via at least one of the fixtures; 5670708

pressurizing the fluid in the pre-tester tube lumen to pulsatile pressures found in the human vascular system; 5670708

measuring the exterior diameter of the pre-tester tube at different pressures; 5670708

recording the data on the measured exterior diameter of the pre-tester tube; 5670708

sealingly coupling opposed free ends of a tester tube onto fixtures of a tester, the tester tube having a lumen; 5670708

25 positioning within the tester tube a stent or stented graft of the same kind as was pre-tested in the pre-tester tube; 5670708

providing a fluid to the tester tube lumen via at least one of the fixtures of the tester; 5670708

pressurizing the fluid in the tester tube lumen at a pulsed rate; and 5670708

measuring the exterior diameter of the tester tube while controlling the fluid pressure based on the recorded data. 5670708

18. The method of claim 17, wherein the fluid pressure within the tester tube lumen is controlled to expand the diameter of the tester tube to the same dimension as the measured diameter of the exterior diameter of the pre-tester tube.

5 19. The method of claim 18, wherein the pre-tester tube lumen is pressurized to both normal and abnormal pulsatile pressures found in the human vascular system, and the tester tube lumen is pressurized at a pulsed rate based on the measured exterior diameter of the pre-tester tube to simulate both normal and abnormal compliance conditions.

20. The method of claim 17, wherein the pre-tester tube is made of animal tissue.

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